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TITLE: Stable liquid composition containing urate oxidase and lyophilized composition for its preparation

DATE-ISSUED: September 22, 1998

INVENTOR-INFORMATION:

| NAME | CITY | STATE | ZIP CODE | COUNTRY |
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US-CL-CURRENT: 424/94.4; 424/94.3

CLAIMS:

We claim:

1. A physically stable, pharmaceutically acceptable liquid composition comprising urate oxidase, and from 0.1 mg/ml to 10 mg/ml of Poloxamer 188, in buffered aqueous medium.

2. The composition according to claim 1, comprising between 0.5 mg/ml and 5 mg/ml of Poloxamer 188.

3. The composition according to claim 1, additionally comprising alanine.

4. The composition according to claim 3, wherein the amount of alanine is between 1 mg/ml and 50 mg/ml.

5. The composition according to claim 1, additionally comprising mannitol.

6. The composition according to claim 5, wherein the amount of mannitol is between 1 mg/ml and 50 mg/ml.

7. The composition according to claim 1, additionally comprising alanine and mannitol.

8. The composition according to claim 7, comprising from 1 to 50 mg/ml of alanine and from 1 to 50 mg/ml of mannitol.

9. The composition according to claim 8, comprising 15.9 mg/ml of alanine and 10.6 mg/ml of mannitol.

10. The composition according to claim 1, which is isotonic.

11. The composition according to claim 1, comprising a sodium phosphate buffer.

12. The composition according to claim 1, wherein the concentration of the buffer is between 5 mM and 100 mM.

13. The composition according to claim 1, wherein the pH is between 7.5 and 8.5.

14. The composition according to claim 1, additionally comprising one or more preservatives selected from the group consisting of phenol, benzyl alcohol, metacresol, methylparaben, propylparaben, a benzalkonium chloride and benzethonium chloride.

15. The composition according to claim 1, obtained by dissolving a lyophilisate comprising urate oxidase in an aqueous solvent.

16. The composition according to claim 1, which is sterile and injectable in man or in animals by the subcutaneous, intravenous or intramuscular route.

17. The composition according to claim 15, in a sterile form injectable in man or animals by subcutaneous, intravenous or intramuscular injection, wherein the lyophilisate consists of 1.5 mg of urate oxidase, 10.6 mg of mannitol, 15.9 mg of L-alanine and 14.32 mg of dibasic sodium phosphate dodecahydrate, and the aqueous solvent consists of 1 mg of Poloxamer 188 and water for injection at q.s. for 1 ml.

18. A lyophilized composition for dissolving in an aqueous solvent comprising Poloxamer and urate oxidase at a weight ratio of 0.01 to 50.

19. The lyophilized composition according to claim 18, additionally comprising a buffer.

20. The lyophilized composition according to claim 18, additionally comprising excipients which provide for the isotonicity of the aqueous solution obtained by dissolving the lyophilisate in an aqueous solvent.

21. The composition according to claim 1 obtained by dissolving a lyophilisate comprising the urate oxidase in an aqueous solvent comprising the Poloxamer 188.

22. The composition according to claim 1 obtained by dissolving a lyophilisate comprising the urate oxidase and the Poloxamer 188 in an aqueous solvent.

23. A composition comprising urate oxidase and 0.1-10 mg/ml Poloxamer 188.

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